

HL7 SPL Working Group Process Communication Forum Telecon

Wednesday, August 26, 2009

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>

Questions on SPL:

ER/DL regulatory questions? Send to edrls@fda.hhs.gov

SPL technical questions? Send to spl@fda.hhs.gov

Meeting Minutes:

Over 4800 SPL are available now on DailyMed

Electronically delisting NDCs/products using SPL

- FDA can't just ask that the National Library of Medicine remove the SPL from their database. Downstream applications won't know why the NDC information has mysteriously vanished.
- There's no longer the capability to send a spreadsheet with the delist information.
- For delisting an entire product, you must now submit an SPL, including a marketing end date for the product.
- Submit the SPL file, include all the NDCs. Immediately submit the SPL again, with an end marketing date for the NDCs that need to be de-listed.
- If we need to change the product code portion of the NDC, creating a new NDC code, it can be filed without needing to delist the previous NDC code.
- Q: For products that are filed only in paper format, do they still need to be delisted via electronic filing? Are they 'automatically delisted' after a few years? *Right now, there is no 'automatic delisting'. The NDC codes will remain in the DRLS files.*
- Q: What if the labeler code no longer exists (was never submitted electronically)? *You have to submit the Labeler Code Request first, then list electronically, then delist electronically.*
- For OTC products, they aren't on DailyMed – why do we have to submit SPL electronically only to immediately delist.
- Can the effective date be used to prevent it from ever presenting on DailyMed?
- Q: If you've already submitted the delisting through the spreadsheet, do you have to resubmit via the SPL route? *If it was already submitted, you don't have to resubmit.*
- If you change the labeler code, you'll need to submit the Drug Listing under a new setid.

- Q: If you have two SPLs, each with different NDCs, for the same active ingredient, can they both be up on DailyMed? If you keep marketing the product, you have to continue keeping the labeling up-to-date
- Different presentations of the same product (same product) on 2 separate Pis. They have the same product code. Ask directly to SPL@fda.hhs.gov

Correcting errors in content of labeling of SPL posted on DailyMed

- Recently, a few companies accidentally sent unapproved label through the Gateway. If there is an error pointed out, you should increase the version number and change the docid and re-submit. If there is a safety issue with the wrong version, you should contact the SPL@fda.hhs.gov and let them know that it should be pushed through to the DailyMed site as quickly as possible.
- FDA is striving to get SPL up to DailyMed within 24 hours.

Requesting changes to product data elements in SPL R3 documents via submission of SPL R4 document.

- There've been a lot of issues with submission of R4 SPL that have differences in product information from the R3 version already on DailyMed.
- When you get the rejection, send a note to SPL@fda.hhs.gov including the CoreId
- Once you move to R4, any changes to packaging or product information will change listing information. It may require changes to the NDC.

Requests for SPL for pending applications

- Recently, some companies may have received a request to update their pending applications. This request was included in some approval letters. We've discussed this internally with OND, and are trying to come up with an answer to the question. Historically, companies were not asked to submit their SPL during negotiations.
- For a CBE, you should include the most recently approved information in the SPL and should be submitted for Drug Listing.
- If folks run into problems, they should contact the SPL@fda.hhs.gov.

Status requests related to valid or invalid SPL submissions

- If you submit an SPL for a marketing category that is not currently on DailyMed, you can send an e-mail to SPL@fda.hhs.gov checking on the validity of the file. You need to include the CoreID (the identifier that is attached to the ESG communications. If you receive a second acknowledgement, that would indicate that the file was invalid.

Transmission of SPL error messages - Gateway and E-mail

- Ideally, we want to receive a receipt and a single acknowledgement
- In some cases, where we have your e-mail address, we will try to contact you outside of the gateway.

- If you get a third acknowledgement with a Word or PDF attachment, this will contain additional information about validation errors.

UNII's needed for substances in cosmetic and homeopathic drugs

- Homeopathic drug substances are not completely indexed in SRS [yet]. FDA is working with authoritative sources from around the world to accurately assign UNII's as quickly as possible. FDA/USP are striving to have the UNII become an international standard. Sometimes SRS team is asking for draft label or product specification to help with the assignment. Submission of product specification sheets may expedite assignment of UNII's (not a requirement)
- The situation is similar for inactive ingredients (the delay in UNII assignments).
- If a product is on hold due to UNII non-assignment, is there any way to get communication from the FDA. If you send an e-mail to the SPL@fda.hhs.gov indicating that a drug is on hold, the FDA will make efforts to expedite the SRS UNII assignment.

Waiver Requests - Complete explanations needed (as stated in final guidance)

- Waiver requests have been coming in because I can't understand the Gateway, or I can't understand the eList process. Waiver requests should include a complete explanation

SPL R4 training sessions (medical gas, cosmetic, OTC, & homeopathic drugs)

- FDA has been working with the CHPA and the PCPC to schedule follow-up training for OTC, and initial cosmetic training (October 2). FDA is planning to provide training sessions weekly through the end of the year for medical gas, cosmetics, OTC, and homeopathic drug sponsors.
- There's been some concern that companies were not being reached (particularly small companies around the world). An e-mail will be sent to 40,000 companies around the world alerting of upcoming trainings. If there is extremely high response for particular topics, there may be several sessions in a single day.

Other questions/items

- ANDA – we are under the impression that we must submit SPL with the original application. Some review divisions handle SPL differently. According to the electronic labeling rule, you should submit SPL. With the application review, the reviewers are concerned with the content of labeling. Requests after approval for the SPL.
- We've had a couple instances of submitting SPL to the Review Division and almost simultaneously through the OC. The OC version had validation errors that caused the company to have to resubmit through the Drug Listing process. Does the file need to be resubmitted through the Application Review process? The Review Division is concerned much more with the Content of Labeling. Lonnie to recheck with Division.
- We were asked to submit SPL, but remove the CBE language before posting. CBE has been filed but not yet approved by the Agency.
- Importing a semi-finished product. Manufacturer must do the drug listing to get the product through Customs; however, if a private label distributor elects to list, the manufacturer does not have to list. If there are problems at the border, include the name and number of the Port of Entry in communications to the SPL@fda.hhs.gov

- Approved generics: who is responsible for listing these? The manufacturer/registrant is required to list using the generics company PI and NDCs. The authorized generic (private labeler) can 'elect' to list.
- Combination package (shrink-wrapped package of two)
- Multiple-listings on the DFARS site. Abbott, Mylan, Teva, Medimmune, Barr, others under the Teva umbrella

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